

Claims:

1. A guaifenesin composition, comprising guaifenesin and a binder and  
5 being in the form of particles, wherein by sieve analysis, based on the total  
weight of the composition, less than about 30 percent by weight of the  
particles exhibit a particle size of greater than about 425 micrometers and  
greater than about 80 percent by weight of the particles exhibit a particle size  
of greater than about 45 micrometers.
- 10 2. The composition of claim 1, wherein the composition comprises  
guaifenesin, a binder, a solubilizer, a glidant and a lubricant.
- 15 3. The composition of claim 1, wherein the composition comprises  
guaifenesin, a polyvinylpyrrolidone binder, a maltodextrin, a silica and stearic  
acid.
- 20 4. The composition of claim 1, wherein the composition, based on the total  
weight of dry ingredients, from about 85 to about 97.5 percent by weight  
guaifenesin, from about 1.0 to about 7 percent by weight of a binder, from  
about 0.2 to about 4 percent by weight of a solubilizer or a disintegrant or a  
solubilizer and a disintegrant, from about 0.1 to about 2 percent by weight of a  
glidant, and from about 0.1 to about 2 percent by weight of a lubricant.
- 25 5. The composition of claim 1, wherein the guaifenesin is in the form of  
particles and wherein by sieve analysis, based on the total weight of the  
guaifenesin particles, from about 10 to about 60 percent by weight of the  
particles exhibit a particle size of from greater than 45 micrometers to less  
than 150 micrometers.

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6. The composition of claim 1, wherein by sieve analysis, based on the total weight of the guaifenesin particles, greater than about 10 percent by weight of the guaifenesin particles exhibit a particle size of greater than 75 micrometers and greater than about 55 percent by weight of the particles exhibit a particle size of greater than 45 micrometers.

7. The composition of claim 1, wherein less than about 25 percent by weight of the particles exhibit a particle size of greater than about 425 micrometers, greater than about 85 percent by weight of the particles exhibit a particle size of greater than about 45 micrometers, and from about 17 to about 55 percent by weight of the particles exhibit a particle size of from greater than 45 micrometers to less than 150 micrometers

8. The composition of claim 1, wherein the composition exhibits a flow rate of greater than or equal to 6.5 grams per second, as measured using a VanKel flowmeter.

9. A guaifenesin composition, comprising from about 85 to about 97.5 percent by weight guaifenesin, from about 1.0 to about 7 percent by weight of a binder, from about 0.2 to about 4 percent by weight of a solubilizer or a disintegrant or of a solubilizer and a disintegrant, from about 0.1 to about 2 percent by weight of a glidant, and from about 0.1 to about 2 percent by weight of a lubricant and being in the form of particles and wherein by sieve analysis, based on the total weight of the composition, less than about 30 percent by weight of the particles exhibit a particle size of greater than about 425 micrometers, greater than about 80 percent by weight of the particles exhibit a particle size of greater than about 45 micrometers, and from about 10

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to about 60 percent by weight of the particles exhibit a particle size of from greater than 45 micrometers to less than 150 micrometers.

10. A guaifenesin composition, comprising from about 85 to about 97.5 percent by weight guaifenesin, from about 1.0 to about 7 percent by weight of a binder, from about 0.2 to about 4 percent by weight of a solubilizer or a disintegrant or of a solubilizer and a disintegrant, from about 0.1 to about 2 percent by weight of a glidant, and from about 0.1 to about 2 percent by weight of a lubricant and being in the form of particles and wherein by sieve analysis, based on the total weight of the composition, less than about 25 percent by weight of the particles exhibit a particle size of greater than about 425 micrometers, greater than about 85 percent by weight of the particles exhibit a particle size of greater than about 45 micrometers, and from about 17 to about 55 percent by weight of the particles exhibit a particle size of from greater than 45 micrometers to less than 150 micrometers.

11. A method for making a compressible guaifenesin composition, comprising:
- mixing a mixture comprising guaifenesin, a binder and water to form agglomerates;
  - drying the agglomerates to form dried particles;
  - classifying the dried particles into first particles having particle sizes less than or equal to a selected classification limit and second particles having particle sizes greater than the classification limit;
  - milling the second dried particles to reduce their size to less than the classification limit; and
  - combining the milled second particles with the first particles to form the guaifenesin composition.

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12. The method of claim 11, wherein the mixing under high shear conditions is conducted in a vertical high shear mixer.
- 5 13. The method of claim 11, wherein, prior to drying, the agglomerates are wet milled under conditions effective to reduce the size of the agglomerates.
14. The method of claim 11, wherein the drying is conducted at less than 65°C.
- 10 15. The method of claim 11, wherein the drying is conducted in a fluidized bed at less than 65°C and a fluidization gas flow rate of from about 1300 to about 5000 cubic feet per minute.
- 15 16. The method of claim 11, wherein the classification limit is greater than or equal to 850 micrometers.
17. The method of claim 11, wherein the classification limit is greater than or equal to 1.18 millimeters.
- 20 18. The method of claim 11, wherein the second dried particles are dry milled in a conical mill.
- 25 19. The method of claim 11, wherein by sieve analysis, based on the total weight of the composition, less than about 30 percent by weight of the particles of the guaifenesin composition exhibit a particle size of greater than about 425 micrometers, greater than about 80 percent by weight of the particles guaifenesin composition exhibit a particle size of greater than about 45 micrometers.

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20. The method of claim 19, wherein by sieve analysis, based on the total weight of the guaifenesin particles, from about 10 to about 60 percent by weight of the particles exhibit a particle size of from greater than 45  
5 micrometers to less than 150 micrometers.

21. A method for making a compressible guaifenesin composition, comprising:  
mixing a mixture comprising guaifenesin, a binder, a solubilizer or a  
10 disintegrant and water to form agglomerates,  
wet milling the agglomerates,  
drying the wet milled agglomerates to form dried particles,  
classifying the dried particles into first particles having a particle size of less or equal to a selected classification limit of greater than 850 micrometers  
15 and second particles having a particle size greater than the classification limit,  
dry milling the second dried particles to reduce their size to less than the classification limit, and  
combining the milled second particles with the first particles to form the guaifenesin composition and wherein by sieve analysis, based on the total  
20 weight of the composition, less than about 30 percent by weight of the particles of the composition exhibit a particle size of greater than about 425 micrometers, greater than about 80 percent by weight of the particles of the composition exhibit a particle size of greater than about 45 micrometers, and  
25 from about 10 to about 60 percent by weight of the particles of the composition exhibit a particle size of from greater than 45 micrometers to less than 150 micrometers.

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22. A method for making a guaifenesin dosage form, comprising compressing a guaifenesin composition, said composition comprising guaifenesin and a binder and being in the form of particles and wherein by sieve analysis, based on the total weight of the composition, less than about 30 percent by weight of the particles exhibit a particle size of greater than about 425 micrometers and greater than about 80 percent by weight of the particles exhibit a particle size of greater than about 45 micrometers.
23. The method of claim 22, wherein by sieve analysis, based on the total weight of the composition, and from about 10 to about 60 percent by weight of the particles exhibit a particle size of from greater than 45 micrometers to less than 150 micrometers.
24. The method of claim 22, wherein the guaifenesin composition exhibits a flow rate of greater than or equal to 6.5 grams per second, as measured without vibration using a VanKel flowmeter.
25. The method of claim 22, wherein guaifenesin dosage forms made by compressing the guaifenesin composition at a compressive force of less than or equal to 1.5 tons exhibit a hardness of greater than 15.0 kiloponds.
26. The method of claim 22, wherein guaifenesin dosage forms made by compressing the guaifenesin composition at a compressive force of less than or equal to 2.5 tons exhibit substantially no capping.
27. The method of claim 22, wherein guaifenesin dosage forms made by compressing the guaifenesin composition at a compressive force of from about 0.5 ton to 2.5 tons exhibit less than 1.0% friability.

28. The method of claim 22, wherein prior to the step of compressing, the guaifenesin composition is blended with one or more co-active ingredient selected from pseudoephedrine hydrochloride, dextromethorphan  
5 hydrobromide, chlorpheniramine maleate and acetaminophen.

29. A method for making a guaifenesin dosage form, comprising compressing a guaifenesin composition, said composition comprising guaifenesin, a binder, a solubilizer, a glidant and a lubricant and being in the  
10 form of particles wherein by sieve analysis, based on the total weight of the composition, less than about 30 percent by weight of the particles exhibit a particle size of greater than about 425 micrometers and greater than about 80 percent by weight of the particles exhibit a particle size of greater than about 45 micrometers, and from about 10 to about 60 percent by weight of the  
15 particles exhibit a particle size of from greater than 45 micrometers to less than 150 micrometers, wherein the composition exhibits a flow rate of greater than or equal to 6.5 grams per second, as measured without vibration using a VanKel flowmeter, wherein dosage forms made by compressing the composition at a compressive force of less than or equal to 1.5 tons exhibit a  
20 hardness of greater than 15.0 kiloponds, wherein dosage forms made by compressing the composition at a compressive force of less than or equal to 2.5 tons exhibit substantially no capping and wherein dosage forms made by compressing the composition at a compressive force of from about 0.5 ton to 2.5 tons exhibit less than 1.0% friability.

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